

# UNITED STATES AIR FORCE RESEARCH LABORATORY

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## Variability of Hearing Protector Attenuation Measurement Data: A View of Interlaboratory Studies

Charles W. Nixon

VERIDIAN  
5200 Springfield Pike, Suite 200  
Dayton OH 45431-1289

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Human Effectiveness Directorate  
Crew Survivability and Logistics Division  
2610 Seventh Street  
Wright-Patterson AFB OH 45433-7901

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FOR THE COMMANDER



THOMAS J. MOORE, Chief  
Crew Survivability and Logistics Division  
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13. ABSTRACT (Maximum 200 words) The goal of national and international measurement standards is to provide consensus procedures that produce reliable qualitative and quantitative data. A standard measurement procedure is expected to produce similar results when implemented by different users. The effectiveness of hearing protection devices in noisy environments is determined using procedures that comply with hearing protector attenuation measurement standards. However, the values collected under these specified conditions do not show the expected levels of repeatability. Results in one laboratory are usually not repeated in others. The inability to achieve the expected similarity of results is attributed to the numerous sources of variability in the measurement processes and facilities. Some sources of variability cannot be eliminated; others may be minimized with knowledge about the sources and proper actions initiated to counteract them. Variability is so extensive in these data that utilization of the results can increase the probability of incorrect conclusions. Variability among interlaboratory comparison studies with each using the same measurement standard are reviewed and discussed. This discussion is intended primarily, but not exclusively, for those who may not be fully informed about the measurement of hearing protector attenuation.				
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## PREFACE

This work was performed for the Bioacoustics and Biocommunications Branch, Biodynamics and Biocommunications Division, Crew Systems Directorate, Armstrong Laboratory, Human Systems Center, Air Force Materiel Command, Wright-Patterson AFB, OH, under engineering services contract F41624-95-C-6014 with Systems Research Laboratories, 2800 Indian Ripple Road, Dayton, OH. It was accomplished during the period from January 1997 to January 1998. The report relates directly to biocommunications research on the development, measurement, and use of personal devices that provide protection of operational personnel from noise-induced adverse effects on hearing and performance. It addresses the measurement of performance of hearing protection devices and reasons for the inability of laboratories to obtain the same results when independently measuring the same hearing protection device. The project manager for the biocommunications effort was Richard L. McKinley, currently of the Noise and Vibration Branch (HESN), Crew Survivability and Logistics Division, Human Effectiveness Directorate, Air Force Research Laboratory. The overall report was improved by the excellent technical editing of Ms. Marty Luka of Systems Research Laboratories.

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# VARIABILITY OF HEARING PROTECTOR ATTENUATION MEASUREMENT DATA: A VIEW OF INTERLABORATORY STUDIES

## BACKGROUND

One goal of national and international standards is to provide consensus procedures for the reliable measurement of quantitative and qualitative values. The same standard measurement procedures are expected to produce similar (reliable) results, although similar is not defined. Ideally, data collected by different users of the same standard should be similar enough to be interchangeable. The sound attenuation of hearing protection devices is measured using the procedures of nationally and internationally approved standards. Sound attenuation performance is described in terms of the mean sound attenuation and standard deviation values. These data are transformed into metrics that assign each hearing protection device a numerical effectiveness rating such as the single-number Noise Reduction Rating (NRR) and other single and multiple-number ratings (20). These numerical ratings are the predominant criteria used in the selection of hearing protectors to support hearing conservation programs (estimate allowable daily exposures, etc.), to estimate voice communications in noise (estimate speech to noise ratio, etc.) and to prevent noise-induced hearing loss (estimate noise level under hearing protector).

Hearing protector attenuation values collected with procedures that comply with the national and international standards do not show the expected levels of repeatability. Variability of the measured sound attenuation data is so extensive that results obtained in one laboratory are usually not repeated in other laboratories. Procedures established to rank order the effectiveness of hearing protection devices fail to do so across laboratories. Also, the sound attenuation obtained under the ideal laboratory conditions required by the standards is much higher than that found for the same devices in the workplace. Despite this, the attenuation data have been used unsatisfactorily to estimate (calculate) the levels of noise at the ears of workers in occupational situations (EPA). A review of numerous comparison studies reveals that the field attenuation of earplugs is only about 25 percent and earmuffs only about 60 percent of the laboratory measured values. An explanation of these large discrepancies between laboratory and field attenuation data is provided in this comprehensive review by Berger et al. (9). Field attenuation data from several different studies are reported in the NIOSH 1994 hearing protector compendium (20).

The inability to achieve the expected similarity of results among users of the same standards is attributed to sources of variability in the measurement process. Variability in the measured data occurs for many reasons and cannot be eliminated, particularly from studies made with human subjects. Knowledge of sources of variability allows users to minimize the effects and to determine the degree of confidence in the procedure and in the results. Results are subsequently used in important decision making in the hearing protection device phases of hearing conservation programs. Excessive variability can interfere with decision making, increase the probability of incorrect conclusions, and render the data useless for inferential and practical applications. Although results obtained with many standard measurement procedures may not be valid, they are expected to be repeatable.

## PURPOSE

This report reviews variability in hearing protector attenuation data obtained with common measurement procedures. The approach was to revisit selected references and the results of five interlaboratory studies conducted in the United States and Europe. Participating laboratories in each study reported the use of their national or international measurement standard in effect at that time. All laboratories in each interlaboratory group measured the same hearing protection devices. Sound attenuation and variability data of specific hearing protectors were compared within and between interlaboratory studies. Many of the sources of variability that influence the measurement of sound attenuation are noted. The interlaboratory studies evaluated only conventional passive hearing protection devices. These devices provide sound attenuation to the wearer by applying acoustical impedance, sound transmission loss, absorption, and dissipation materials in the forms of earplugs and earmuffs. Although hearing protector effectiveness metrics are cited, the focus remains on sources of variability in the measurement procedures. This information is intended primarily for those who may not be fully informed about the measurement of sound attenuation of hearing protection devices.

## STANDARDS

The sound attenuation provided by hearing protection devices is measured using procedures standardized by organizations in individual nations, such as the American National Standards Institute (ANSI) in the United States and the International Standards Organization (ISO) in Geneva for the world-wide community. The most common procedure measures the hearing threshold levels of human subjects for several test frequencies with the listener's ears open (unoccluded) and with the ears occluded by the hearing protector under test. The sound attenuation provided by the device is the measured difference between the ears-open and ears-occluded hearing threshold level values. It is the amount that the open ear test sound is reduced by the hearing protection device or, alternatively, the amount that the test sound must be increased above the open ear threshold to be heard by a subject wearing the hearing protector. A complete test uses from 10 to 20 listeners. This basic procedure is the real-ear attenuation at threshold (REAT) measurement method and its use is almost universal. The real-ear attenuation procedures are popular because of the face validity of the method; it measures the sound attenuation obtained by human subjects wearing hearing protection devices in noise. The sound attenuation of hearing protection devices is usually reported in measures of central tendency (mean) and variance (standard deviation), and sometimes with percentile and quartile information.

The REAT is a subjective test that is the basis for both the national and the international standards. The mandated measurement standard in the United States is ANSI S3.19-1974 (2) and in Europe is ISO 4869-1, 1990 (15). The methods are fundamentally the same except for number of subjects (16 with one trial in Europe and 10 with 3 trials in the U.S.), the fitting procedure by the experimenter in the U.S., and elimination of feedback from the experimenter in the ISO standard. Other standard procedures are available for measuring hearing protector performance. The ANSI Standard S12.6-1984 (3) was recently revised to include the Method B procedure and re-issued as ANSI S12.6-1997 (5). Method B is a real-ear attenuation at threshold

method, called the subject fit method, with unique subject selection, experimenter role, and hearing protection fitting procedures.

Two standard physical methods of measuring the insertion loss of circumaural protectors are described in ANSI S12.42-1995 (4). One method measures the levels of test signals with a miniature microphone at the entrance to the ear canal of human subjects with and without the circumaural hearing protector. The other measures the levels of test signals with a microphone positioned at the site of the entrance to the ear canal of an acoustical test fixture (dummy head) with and without the hearing protector in place. The physical measurement procedures were developed to provide quick measurements of attenuation for purposes of design and development and to allow measurements to be made in high levels of noise. At this time, only the subjective method in ANSI S3.19-1974 is authorized by the federal government (EPA) for use in measuring the attenuation of hearing protection devices. Studies showing that laboratory data overestimate hearing protector attenuation in the workplace prompted the government to direct that laboratory-derived single number ratings be reduced by 50 percent when estimating workplace attenuation (21).

## INTERLABORATORY STUDIES

Laboratory measurement procedures are standardized to provide corresponding results when implemented within and among different countries. Interlaboratory studies were organized and executed to measure the actual correspondence of data collected among selected organizations. Each study was comprised of a group of participants, or laboratories, who used a common measurement procedure to individually evaluate the same hearing protectors. The individual goals varied somewhat, but most included a focus on the repeatability of the data measured separately by the participants. The dispersion of the mean and standard deviation data from five interlaboratory studies was reviewed and factors noted that could have contributed to the variance of the data. The interlaboratory study data examined in this review are tabulated in Appendices A, B, and C.

### U.S. Air Force Survey (1976)

An early comparison of the repeatability of hearing protector attenuation data was made by the Air Force Aerospace Medical Research Laboratory in 1976. Hearing protector mean attenuation and standard deviation data were retrieved from different laboratories that had completed sound attenuation measurements on several hearing protection devices. Attenuation measurements in these laboratories were based on the American National Standards Z24.22 - 1957 methodology (1). Test stimuli were discrete tones and measurements were made in anechoic spaces. The experimenter provided direct assistance in the selection and fitting of the hearing protection devices. Data on six devices were collected from four laboratories. Two types of earplugs and one earmuff were included in this analysis. The variability of these independently measured data was not as large as expected. Earmuff data were less variable than those of earplugs, and it was suggested that consideration be given to the development of separate criteria for earplugs and for earmuffs.

Data for the Air Force survey were obtained from the Air Force Aerospace Medical Research Laboratory, Ohio; U. S. Army Medical Research Laboratory, Alabama; Arcon Laboratory, and Paul Michael and Associates, Pennsylvania. Participants in all of the interlaboratory studies, and their designations in this report, are identified in Appendix D.

#### Environmental Protection Agency (EPA) Study (1982)

In 1979, the Environmental Protection Agency required manufacturers to label their hearing protection devices with the single-number NRR described earlier as derived from laboratory attenuation and standard deviation data (13). The NRR is subtracted from the C-weighted level of a noise to provide an estimate of the A-weighted level of the noise under the hearing protector for hearing conservation purposes. The NRR must be reduced an additional 7 dB to account for spectral variations when it is subtracted from the A-weighted level of the noise. The EPA had the option to require the NRR value of any hearing protector to be validated by a repeat test value that was very close to the original test value. Validation failures required corrective actions and could also include penalties. However, the variability of the results between the original and the audit test, due to factors other than the hearing protector, were greater than the allowable variation, making the audit test invalid. An understanding of the variability of measured data is vital to the just and equitable implementation and utilization of hearing protection devices and to descriptions of their performance.

The initial planned study of interlaboratory variability of hearing protector attenuation was sponsored by the U.S. Environmental Protection Agency and reported in 1982 (6). Four different hearing protection devices were evaluated by seven participating laboratories in a round robin test program. Data already on file with the EPA from an eighth laboratory were also included in the analyses. The laboratory measurement procedures were accomplished using ANSI S3.19-1974 "Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Ear Muffs" in accordance with EPA requirements (13).<sup>\*</sup> This ANSI method used third-octave bands of noise as test stimuli, made measurements in diffuse sound fields, and the experimenter selected the hearing protector and fit it for the subject. However, the ANSI S3.19-1974 required experimenter fit was changed for the EPA study to an experimenter-supervised fit that required the fitting for the measurements of the hearing protector attenuation to be done by the subject instead of the experimenter. Overall, significant variability was observed in both mean attenuation and standard deviation values. The variability of measured sound attenuation was so great, with a maximum dispersion of 18 decibels at one point, that even the rank ordering of hearing protection devices across laboratories was not possible. The primary sources of variance were reported as subject selection and training, inability of experimenters to obtain a consistent acoustic fit of hearing protection devices across subjects, and treatment of the subject response data (6).

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<sup>\*</sup> This standard (S3.19-1974) was updated in 1984 (S12.6-1984) and again in 1997 (S12.6-1997). The EPA hearing protection regulatory document has not been revised. Consequently, S3.19-1974 remains the mandated measurement standard for commercial distribution of hearing protection devices in the United States.

The eight participants in this study were EAR Division Acoustics Laboratory, U. S. Army Aeromedical Research Laboratory, Intest Laboratory, Kresge Hearing Research Laboratory, Paul L. Michael and Associates, Naval Aerospace Medical Research Laboratory, Darrell Teter and Associates, and William Wadsworth, Worcester Polytechnic Institute.

#### Nordic Study (1984)

The Nordic interlaboratory study accomplished in 1984 was the only true round robin study. The same set of four earmuff devices was measured, in turn, in each of the four laboratories. Each laboratory received its own set of earplugs (22). Hearing protectors were conditioned before testing by storage at temperatures of 65 degrees Celsius for 72 hours and at minus 18 degrees for four hours. The studies were accomplished in accordance with the acoustical measurements portion of the common Nordic standard that was reported to be essentially the same as ISO 4869:1981 (14). This real-ear attenuation procedure used third-octave bands of noise as test stimuli, made measurements in non-directional sound fields, and used the experimenter-supervised fit of the hearing protectors. This Nordic standard procedure was relatively new and had not been accepted in its final form by the Nordic countries. The objectives of the study were to locate and quantify the origins of discrepancies in the measurement procedures affecting the data and to resolve them to minimize variability. Overall, repeated measurements in the same laboratory and between laboratories showed a high level of repeatability. Mean values for earplugs were not significantly different among laboratories, except for one device that experienced fitting problems. Significantly different mean values for earmuffs were found among the laboratories.

The participating laboratories were the Department of Technical Audiology, Technical University, Sweden; The Audiological Laboratory, Norway; Department of Industrial Hygiene and Toxicology, Finland; and The Acoustics Laboratory, Technical University (DTH), Denmark.

#### European Economic Community (EEC) Study (1986)

The European Economic Community recognized the importance to its members that hearing protection data collected in one country correspond with that obtained in other countries. The EEC sponsored the United Kingdom National Physical Laboratory (NPL) interlaboratory study reported in 1986 (23). Four earmuff devices and one earplug were evaluated by five participating laboratories in the intercomparison study. All devices were initially evaluated at the NPL, a subset of these was sent to each of the participating laboratories, and selected devices were reevaluated after their return to NPL. The laboratory measurement procedures were accomplished in accordance with "Measurement of Sound Attenuation of Hearing Protectors," ISO 4869:1981. This real-ear attenuation procedure used third-octave bands of noise as test stimuli, made measurements in non-directional sound fields, and used the experimenter-supervised fit of the hearing protectors. The purpose of the study was to evaluate the efficacy of the hearing protector measurement standard that was current at that time. General results indicated that repeated measurements in the same laboratory showed a high level of consistency. Significantly different mean values for earmuffs were found among the laboratories. EAR earplug means were similar.

The participating laboratories were The Acoustics Laboratory, Technical University, (DTH), Denmark; Institut National de Recherche et de Securite (INRS), France; National Physical Laboratory (NPL), United Kingdom; Physikalisch-Technische Bundesanstalt (PTB), Federal Republic of Germany; and TNO Research Institute for Environmental Hygiene (TNO), Netherlands.

#### American National Standards Institute WG S12.11 Interlaboratory Study (1993)

The WG S12.11 interlaboratory study was completed in the United States in 1994. This study differed substantially from those of prior interlaboratory studies that analyzed the competency of the consensus real-ear measurement standards that were in use at those times. The goal of this study was to evaluate laboratory-based real-ear attenuation at threshold procedures that can be used to estimate attenuation achievable by informed and motivated users wearing hearing protection devices under field conditions (12). Specifically, it was to establish a measurement procedure that would estimate the protection that can be, or is being, obtained in the top 10 to 20 percent of today's hearing conservation programs. The S12.11 study was prompted by research cited earlier showing that hearing protector performance in the workplace is significantly less than the attenuation reported in laboratory measurements (9) and that indicated by NRR values (7). Primary sources of these differences were identified as the interpretation and implementation of the standards, the selection, training, and instructions given to the subjects, and the characteristics and influences of the experimenter on subject performance. Major differences from other REAT methods were in the areas of experimenter involvement and subject selection.

The real-ear attenuation at threshold procedure was modified to minimize and eliminate some of the primary sources of variability and to provide attenuation values that were more realistic estimates of attenuation found in the workplace (5). Third-octave bands of noise were the test signals and measurements were made in a non-directional sound field. The new measurement procedure contrasted sharply with the experimenter-supervised fit of current standards. This procedure used only subjects who were naive with respect to the informed use of hearing protectors. They were provided only the hearing protector and the manufacturer's instructions and were informed to fit the devices without any assistance. All subjects received exactly the same word-for-word guidance and instructions, which were very specific and were memorized and recited or read aloud by the experimenter. No additional oral communication was permitted between the subject and the experimenter. The accuracy, or validity, of the laboratory measured values of the uninformed subjects was evaluated by comparison with the available real world database values (8, 12).

The new procedure was based on the ability of naive subjects to interpret and correctly implement the printed instructions included with the hearing protector by the manufacturer. The manufacturer's instructions were also being evaluated as part of the hearing protector fitting process. The experimenters from the four laboratories reported problems with the instructions from most manufacturers, particularly with the earplug devices. The manner in which subjects selected and fit themselves with the devices varied widely and to such an extent that several subjects reversed the premolded earplugs and inserted them backwards. It was clear that the



manufacturer's instructions were inadequate for most naive subjects using the devices without assistive guidance and that the inadequate instructions contributed to the variability of the data.

The four laboratories complied fully with strict requirements for all aspects of the testing space, instrumentation, and procedures. The responsibilities of the experimenters were very explicit, experimenter influences were minimized, and opportunities were very small for procedures to vary from one laboratory to another. All data were collected in a specified format and analyzed at a central location. The S12.11 uninformed subject fit measurement procedure was approved by the American National Standards Institute and was incorporated as Method B in ANSI S12.6-1997, "Methods for Measuring the Real-Ear Attenuation of Hearing Protectors." The rationale and measurement procedure of Method B are fully described in the ANSI S12.6 standard (5).

The four organizations that participated in the interlaboratory study were EARCAL Laboratory, Cabot Corporation, Indianapolis, IN; U.S. Army Aeromedical Research Laboratory, Ft Rucker, AL; National Institute of Occupational Safety and Health (NIOSH), Cincinnati, OH; and the U.S. Air Force, Armstrong Laboratory, Wright-Patterson AFB, OH.

During the five interlaboratory studies, 16 different hearing protection devices were measured in 24 evaluations in 20 different laboratories. However, only the EAR slow-recovery foam earplug was measured in all studies. The other items appearing more than once were the V51R earplug (three times), and the Optac Optigard and the Amplivox Sonogard earmuffs (twice each). Data were examined only for the EAR and the V51R insert earplugs and a group of four

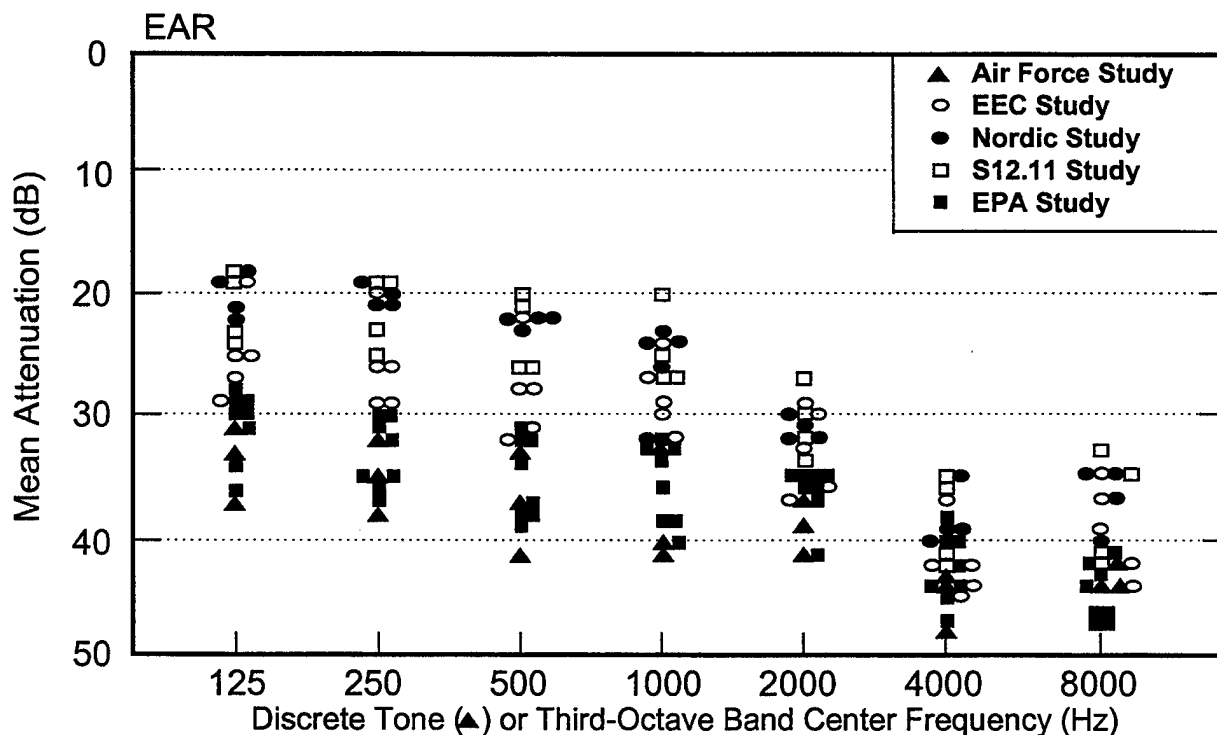


Figure 1. Dispersion of EAR earplug mean attenuation at each test frequency measured by individual laboratories within and across the interlaboratory studies.

dissimilar earmuffs (Optac Optigard, Bilsom UF-1, Mine Safety Appliances MSA Mark II, and MSA Mark IV) representing the five different studies.

The variability of the reported data was assessed in terms of the overall ranges, the mean sound attenuation, and the mean standard deviations. Individual subject data were not reported by most of the laboratories. The number of experimental subjects and repeat measures utilized by the laboratories varied, with 10 subjects and three repeat measurements in the AF survey and EPA studies, 20 subjects with a single measurement in the EEC and Nordic studies, and 24 subjects with a single measurement in the S12.11 study.

## VIEWS OF THE DATA

### Total Ranges of Mean Attenuation

Overall dispersion of mean attenuation values at each of the test frequencies for the three groups of hearing protection devices is shown for all laboratories in Figures 1, 6, and 8. The total range is determined by only the highest and lowest score at each test signal and is considered an unreliable statistic and inferior to other measures of dispersion. However, the interlaboratory numbers are not raw data but are mean scores that have minimized the primary effects of outliers. Also, the number of data points at each frequency is very small and the use of the more reliable interquartile range, which omits 50 percent of the data, is considered not actual. The extreme points of measured sound attenuation data are important to a review of its variability.

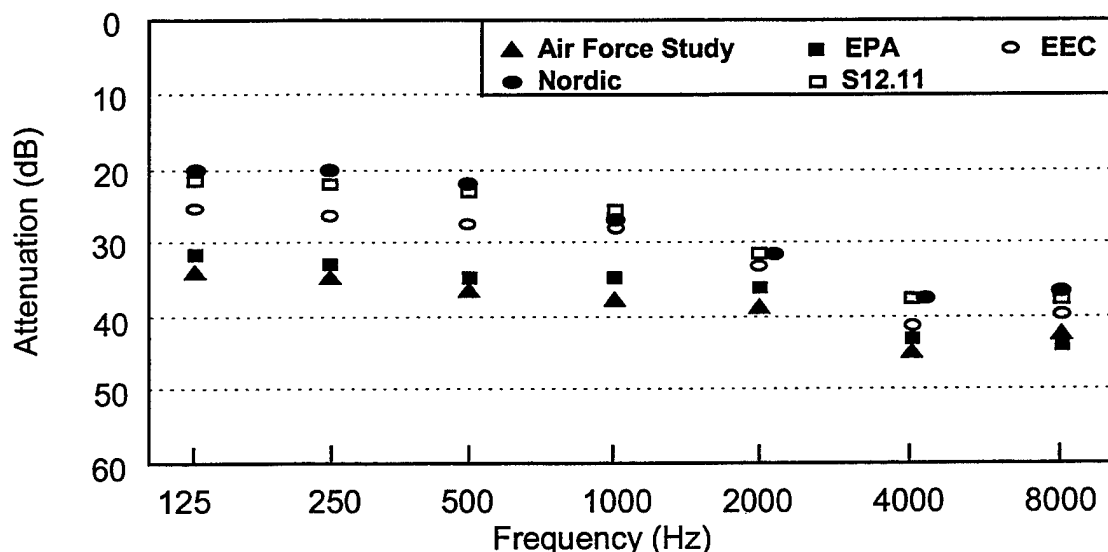


Figure 2. EAR mean attenuation at each test frequency reported for each of the interlaboratory studies. The individual study means retain the same positions relative to one another as shown in Figure 1. The overall ranges are reduced by about 25 percent at the lower frequencies and as much as 50 percent at the higher frequencies.

## EAR

The EAR data in Figure 1 show the ranges of mean attenuation values from the individual laboratories within and across the interlaboratory studies. The overall mean attenuation values for the 5 interlaboratory studies are shown in Figure 2. All studies measured subject hearing threshold levels with and without the hearing protector. The 1976 Air Force survey utilized trained subjects, pure tone test signals, an experimenter fit, and an anechoic space for collecting the attenuation data. The EPA, Nordic, and EEC studies used trained subjects, third-octave bands of noise, an experimenter-supervised fit, and non-directional sound sources. The S12.11 study used subjects who were naive or uninformed about hearing protector use, third-octave bands of noise, manufacturer's instructions only with no sizing or fitting assistance from the

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Table 1. Ranges of EAR mean attenuation (differences between highest and lowest mean attenuation values rounded to whole numbers) for each of the test signals across the individual laboratories in each of the five intercomparison study groups. The ranges across Nordic study laboratories were very low and significantly less at most frequencies than those of the laboratories in the other studies. N = number of laboratories in the study.

	Discrete tones for Air Force study and third-octave band center frequencies for others (Hz)						
	125	250	500	1000	2000	4000	8000
Air Force study (N = 3)	6	6	8	8	4	5	2
EPA study (N = 8)	8	6	7	7	7	9	5
EEC study (N = 5)	10	9	9	7	9	8	9
Nordic study (N = 4)	4	2	1	3	2	5	5
S12.11 study (N = 4)	6	6	6	7	7	7	9

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experimenter, and a non-directional sound source. The ranges of lowest to highest mean attenuation of the EAR data across all laboratories are about 20 decibels at the lower frequencies and 15 decibels at 2000 Hz and above. Within the individual interlaboratory studies, the ranges at each test signal were 5 to 10 decibels except for the Nordic data which showed very low ranges of 1 to 5 decibels over all test signals (Table 1). The lowest interlaboratory study mean attenuation data across all frequencies was observed with the Nordic and S12.11 studies and the highest with the Air Force and EPA studies (Figure 2).

The EAR mean attenuations and standard deviations of the individual laboratories in the Air Force and EPA studies are displayed in Figure 3 and in the other studies in Figure 4. The S12.11, EEC, and Nordic mean attenuation data are similar, with the least variability in the

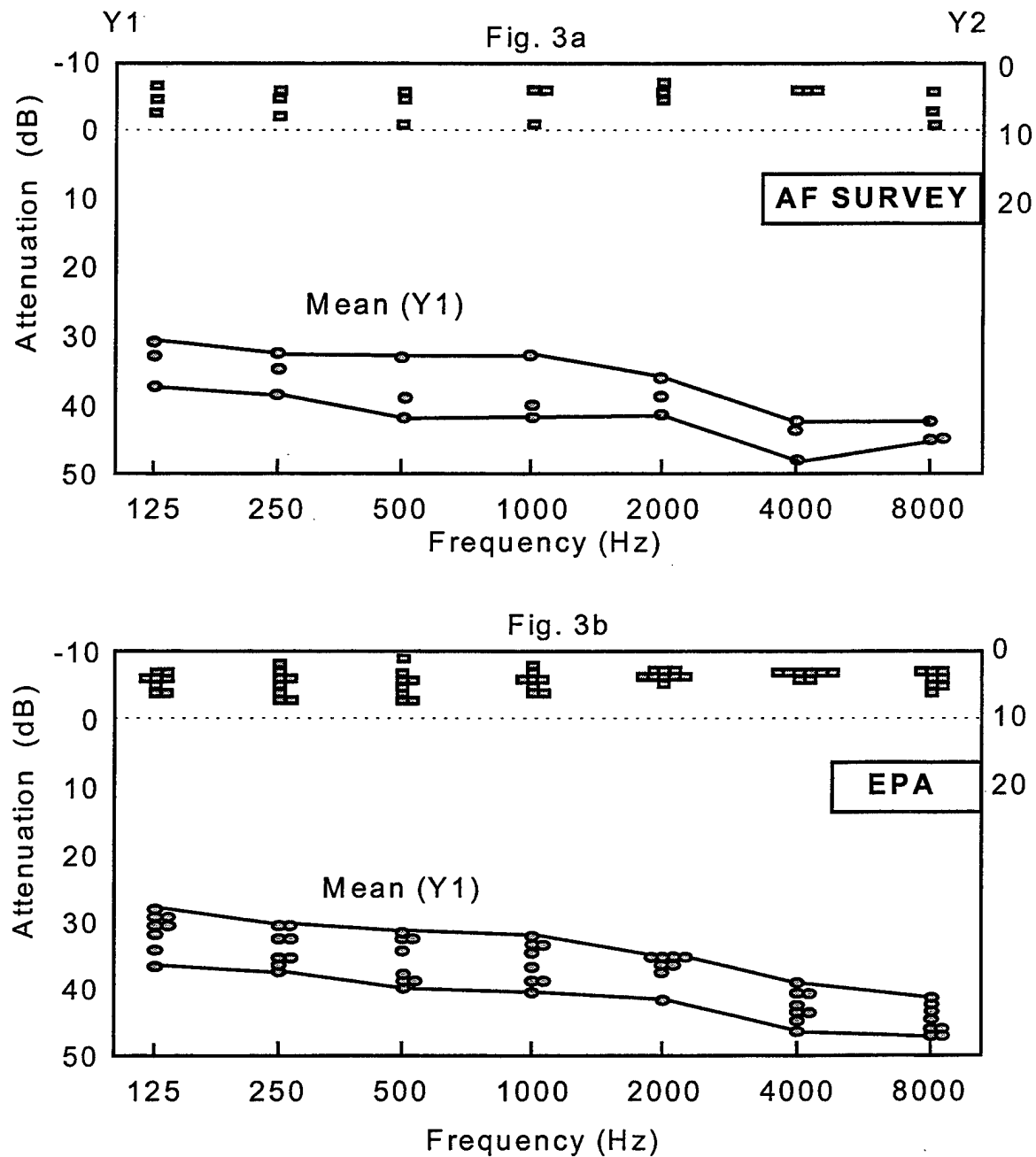


Figure 3. Ranges, means, and standard deviations of the EAR earplug measured by the individual laboratories during the Air Force survey and the EPA intercomparison studies.

Nordic data. This is of interest because the Nordic study utilized the experimenter's supervised subject fit that was expected to produce higher attenuation and lower variability values than the

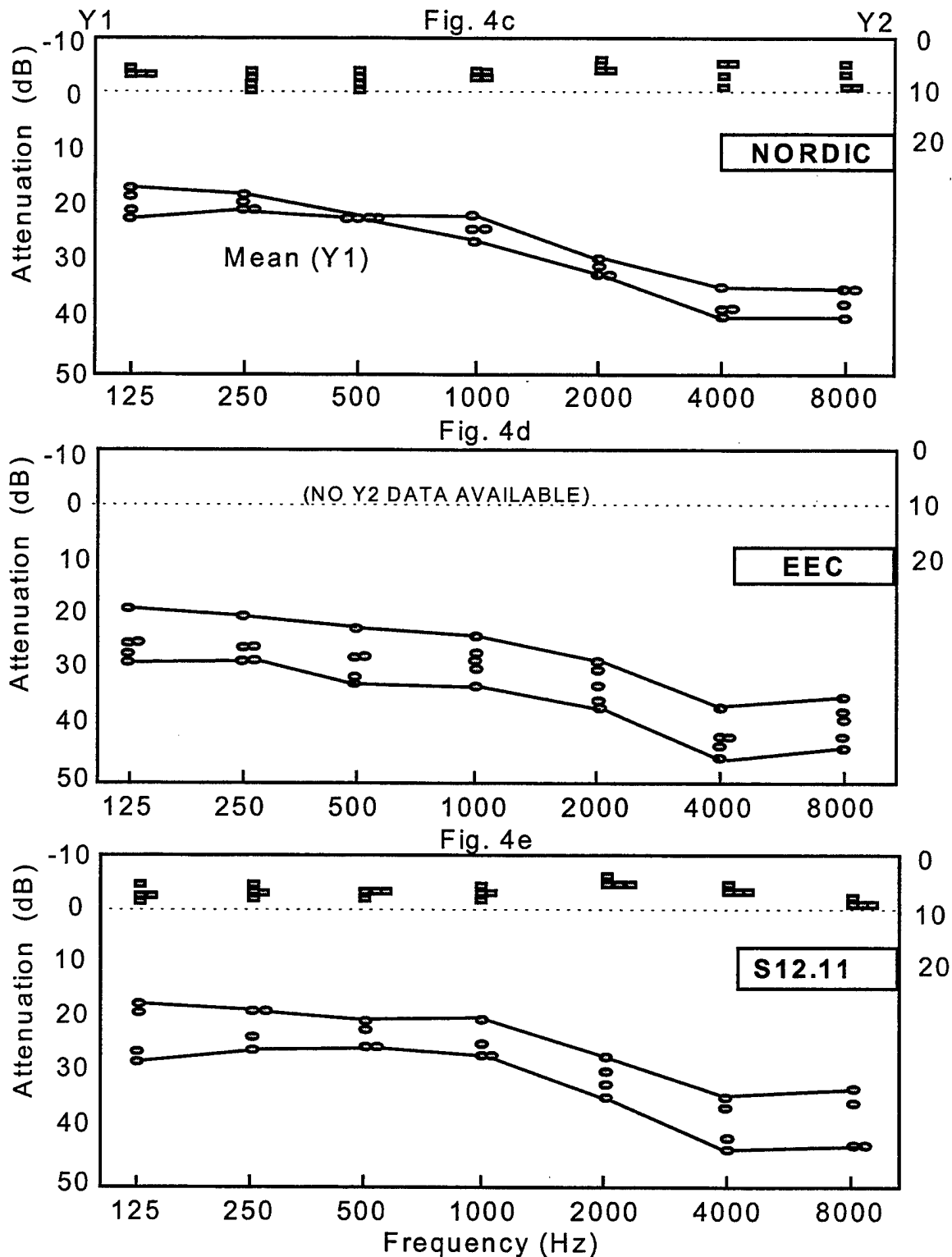


Figure 4. Ranges, means, standard deviations of the EAR earplug measured by the individual laboratories during the Nordic, EEC, and S12.11 studies.

relatively poorer, unaided fittings of the S12.11 naive subjects. The EPA study and Air Force survey data are also similar, showing greater mean attenuation at all frequencies than the other studies. These two sets of data were collected an estimated 10 years apart and each was based a different measurement standard. The S12.11 and Nordic data do not overlap the EPA and Air Force data except at 4000 and 8000 Hz (Figure 1).

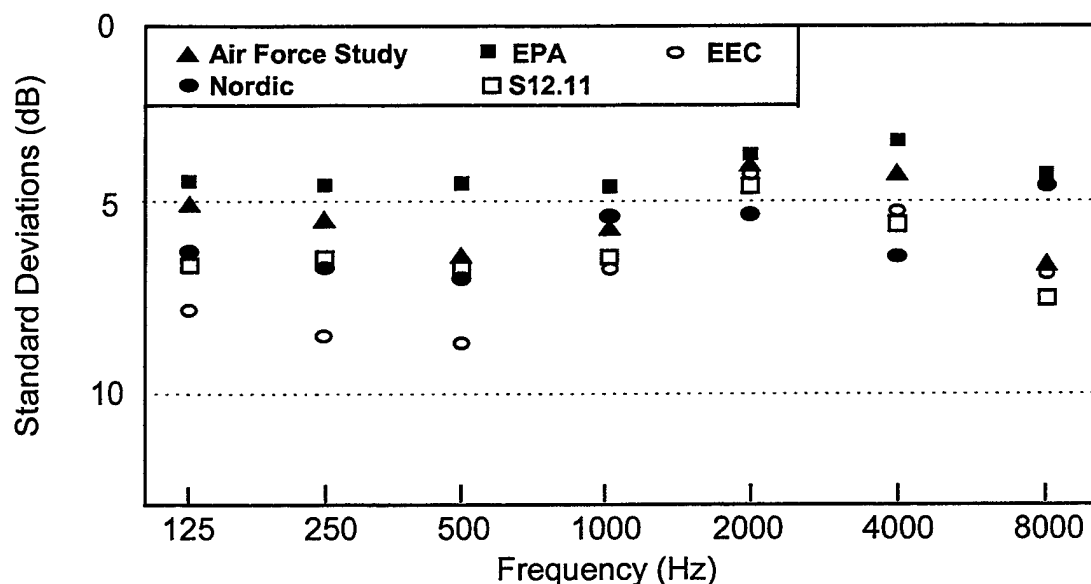


Figure 5. EAR mean standard deviations at each test frequency reported by each of the five interlaboratory studies. The EEC data at the low frequencies suggest subject difficulties with the fitting of the insert earplugs.

The overall mean standard deviations for each of the five interlaboratory studies are shown in Figure 5. The AF and EPA studies with the highest attenuation generally show the lowest standard deviations. The relatively high variability of the S12.11 data was expected because of the unaided fitting of the hearing protectors by naive subjects. Subjects in the EEC study appeared to have difficulty fitting the EAR earplug as reflected in the highest standard deviations at the low test frequencies.

Table 2. EAR mean attenuation data for repeat measurements (DK1 and DK2) at the DTH in the Nordic study (rows 1 and 2), for DTH measurements in the EEC studies, and for the means of the EEC study (row 4).

SOURCE	Third-octave band center frequencies (Hz)						
	125	250	500	1000	2000	4000	8000
Nordic study - DTH/DK1	19.3	19.0	22.4	23.7	31.6	35.3	35.0
Nordic study - DTH/DK2	25.2	26.5	27.7	29.3	34.0	42.3	42.0
EEC study - DTH	26.7	28.9	31.8	31.7	37.2	45.3	44.2
EEC study means	24.9	26.1	28.2	28.4	32.8	42.0	39.6

The Danish Technical University participated in both the Nordic and EEC studies. In the Nordic study, the EAR was measured prior to (DK1) and after (DK2) the measurements of all hearing protectors by the other three laboratories. These data are displayed in Table 2 (rows 1 and 2) with the EAR mean attenuation measured later in the EEC study. Significant increases in mean attenuation over the first (DK1) were found in the second measurement data (DK2). Most of the improvement in attenuation was due to the increased experience obtained by the subjects, who were naive at the first testing and experienced at the second. These subjects had participated in several hearing protector studies during the interim. Other factors were considered by the experimenter: the two sets of earplugs were from different manufacturer's lots, their storage was different, and the second measurement earplugs had been temperature-extreme conditioned prior to the second set of measurements. The post-round robin DK2 mean values were very similar to the EEC study - DTH data and almost identical to the overall EEC study means data (Table 2). The repeatability of these last three data sets is very good.

As noted earlier, the ranking of hearing protectors by the amount of measured attenuation tends to be ordered in individual laboratories. This ranking of the same protectors is not usually alike from one laboratory to another. Also, some laboratories habitually report the highest attenuation values and others the lowest values for the same hearing protector. These variabilities are evident in the data sets of most intercomparison studies, including the EAR, V51R, and earmuff data of Figures 1, 6, and 8, even though the individual laboratories are not identified. In Figure 1, the Air Force and EPA data display the highest mean attenuation values and the Nordic and S12.11 studies the lowest values. The same trends exist for the V51R and earmuff data. The hearing protector rankings of an individual laboratory are attributed to its characteristics and procedures, including personnel.

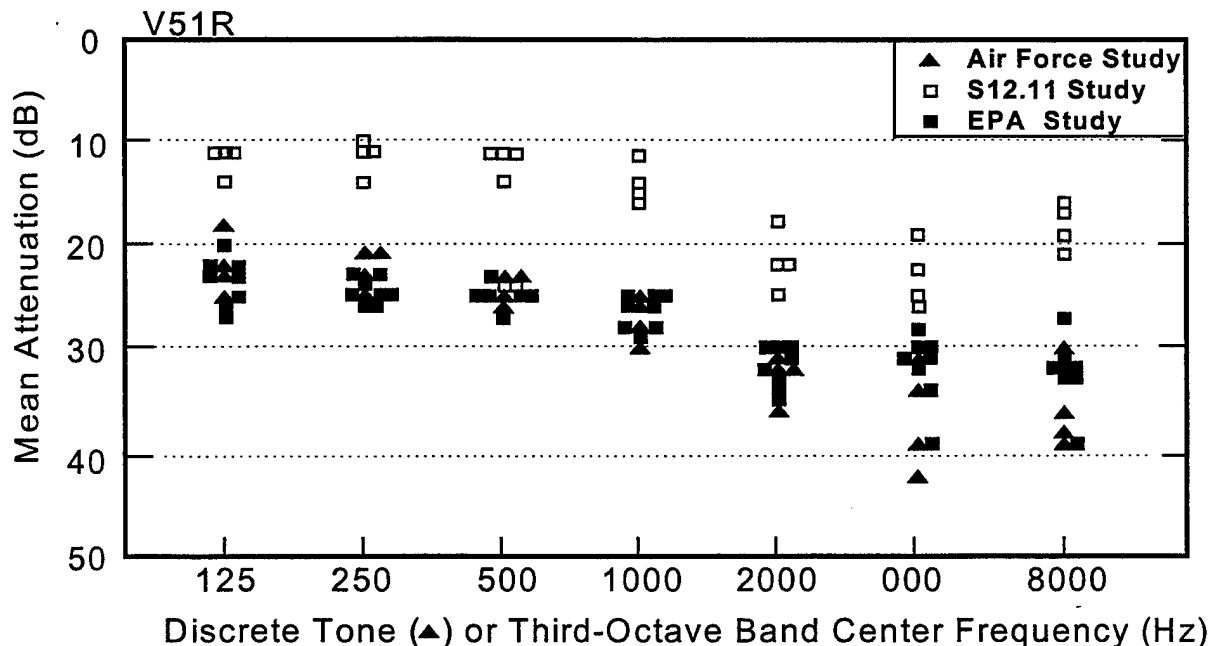


Figure 6. Dispersion of V51R earplug mean attenuation at each test frequency measured by individual laboratories within and across the interlaboratory studies.

## V51R

The overall ranges of mean attenuation of the V51R earplug in the three data sets are summarized in Figure 6. The ranges at the low frequencies are about 16 dB and they increase to about 23 dB at the higher frequencies. The maximum mean attenuation range for the S12.11 data is 7 dB, and for the EPA and Air Force studies is 12 dB.

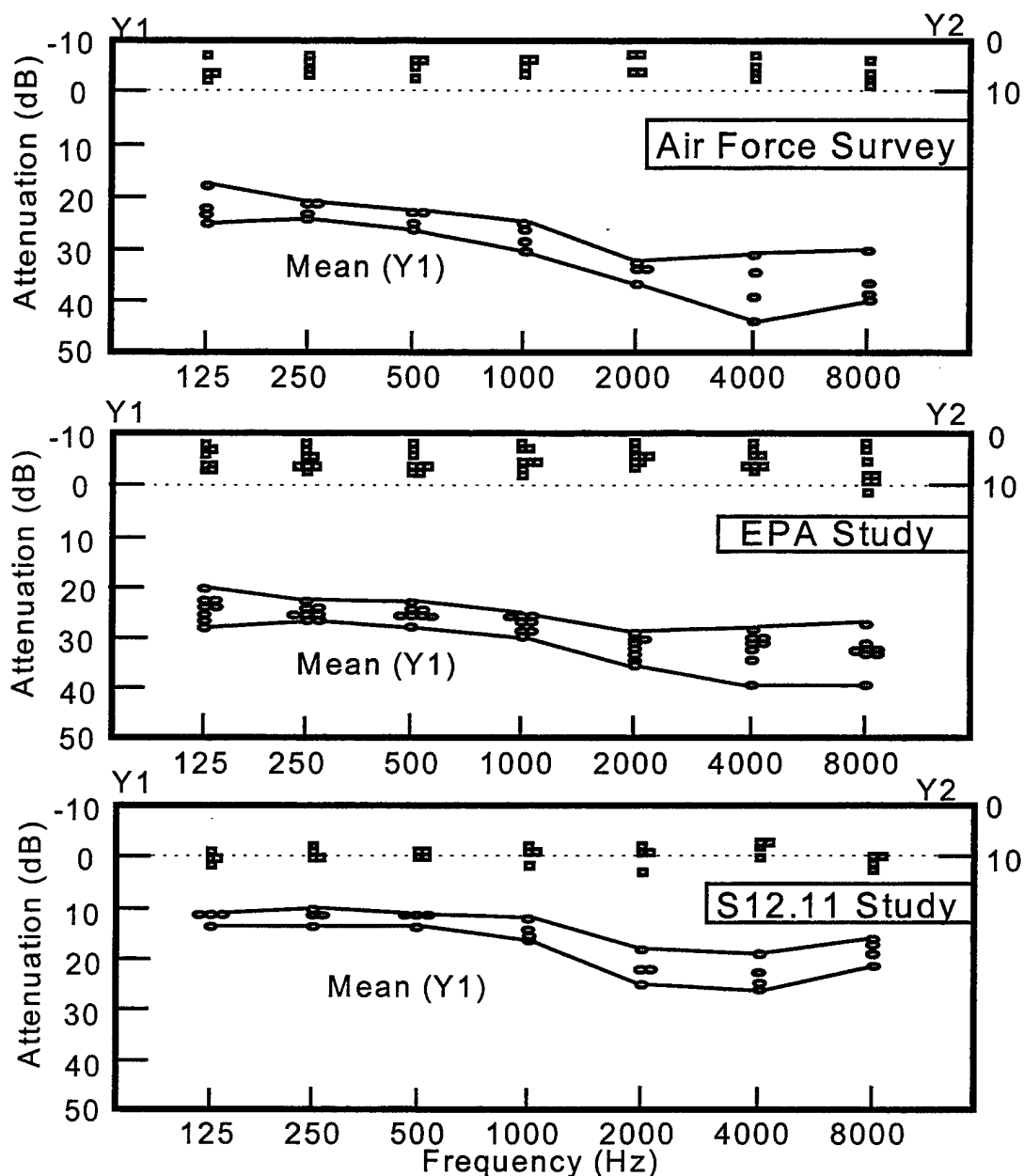


Figure 7. Ranges, means, and standard deviations of the V51R earplug measured by the individual laboratories during the Air Force, EPA, and S12.11 intercomparison studies.



The mean attenuations and standard deviations of the V51R earplug within the three studies are contained in Figure 7. The relative positions of the three groups of laboratories is essentially the same as for the EAR earplug. The maximum mean attenuation in the lower frequencies occurred in the EPA study and in the frequencies of 1000 Hz and above in the Air Force survey. The EPA and Air Force survey data are very similar, with slightly more attenuation at 4000 and 8000 Hz in the Air Force data. Both sets of data show divergence of mean values at the two highest frequencies. The S12.11 data showed about 4 to 8 dB lower attenuation than the others at all frequencies. One S12.11 laboratory showed the highest values of attenuation at all frequencies, which increased the range in this intercomparison study, particularly at the higher frequencies. The S12.11 data did not overlap that of the other laboratories at any frequency. Inspection of the large and highly similar standard deviation values among all S12.11 measurements indicated a significant problem in properly fitting the V51R using only the manufacturer's current instructions. The average value of these standard deviations exceeded 10 dB.

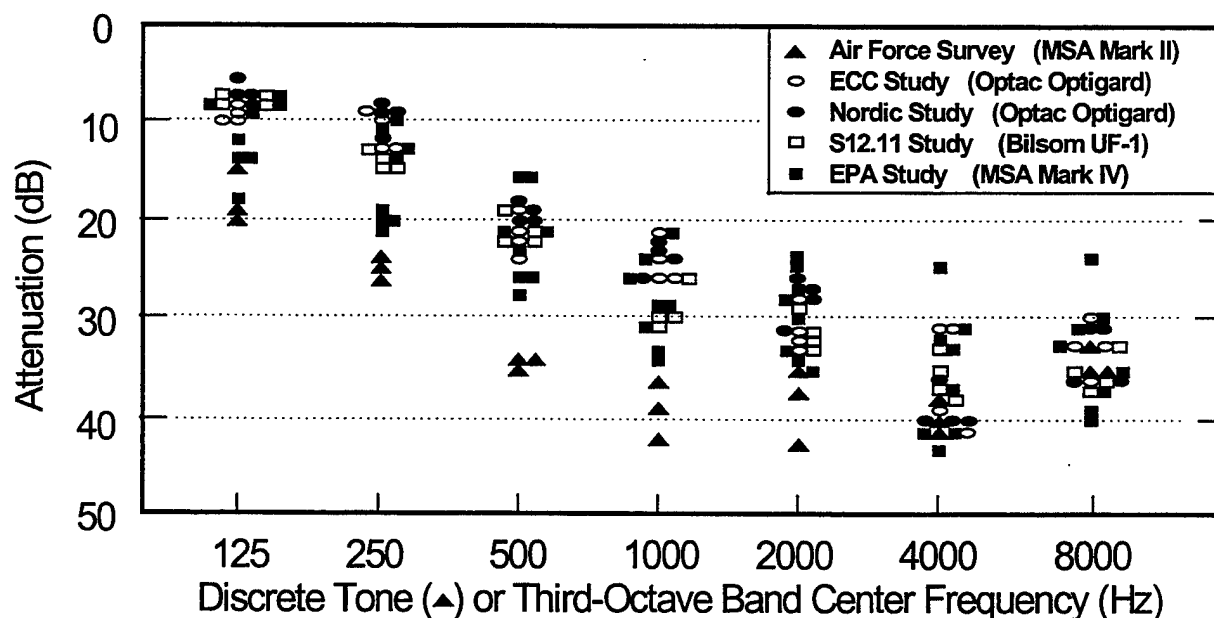


Figure 8. Selected earmuff attenuations at each test frequency measured by the individual laboratory participants in the interlaboratory studies. The poor low-frequency and good high-frequency attenuation typical of conventional passive circumaural hearing protectors is clearly visible in the data, independent of laboratories.

### Earmuffs

The earmuff data represent the performance of a few dissimilar earmuffs, each with its own effectiveness, evaluated by similar real-ear measurement procedures. The typical attenuation curve of passive earmuffs is evident in the data (Figure 8). Relatively poor attenuation at the low frequencies gradually increases with increasing frequency up to 4000 Hz. The attenuation at 8000 Hz is usually equal to or less than at 4000 Hz. The large ranges across the devices reflect the different performance of each type of earmuff as well as the variations among the laboratories. The clustering of the individual participants in each of the

intercomparison studies indicates good consistency with the same device. The larger number of laboratories in the EPA study reflects a little more dispersion of the data than the others.

Table 3. The overall means for the Optac Optigard earmuff reported in the Nordic and EEC studies revealed differences of 1 to 3 decibels except at 2000 Hz.

	Third-octave band center frequencies (Hz)						
	125	250	500	1000	2000	4000	8000
EEC	9.3	11.8	21.6	24.9	32.4	36.8	31.7
Nordic	6.7	9.4	19.2	23.6	28.2	39.0	33.4

The variability among measurements of the same earmuff device by different laboratories is substantially less than with insert and semi-insert devices. The Optac Optigard was evaluated in both the ECC and Nordic studies. The high similarity of the overall mean values of the two measurements is shown in Table 3. This consistency is also obvious in Figure 8 by the clustering and intermingling of the data points of the EEC (open circles) and the Nordic (filled circles) studies. The ranges are small across both sets of data.

Table 4. Differences between mean attenuation (decibels) at each test signal of initial (before Nordic round robin) and repeat measurements (after Nordic round robin) of four dissimilar passive earmuff devices in the DTH laboratory. Repeat measurements were made more than one year following the initial measurements. (Adapted from reference 21)

<u>Earmuff device</u>	Third-octave band center frequencies (Hz)						
	125	250	500	1000	2000	4000	8000
Amplivox Sonogard	0.9	0.6	1.3	0.8	0.8	2.1	1.9
Bilsom Yellow	0.2	2.1	1.9	1.3	0.6	2.1	0.0
Optac Optigard	1.4	0.6	2.1	0.5	0.4	1.3	0.5
Silenta Super	0.9	0.6	0.2	2.4	2.7	2.0	0.6

The variability of repeat measurements of earmuffs in the same laboratory is usually low. The four earmuffs in the Nordic study were measured at DTH prior to the measurement of all devices by all participants and again about 14 months after the initial tests. The differences between the initial and repeat mean attenuation at the individual test frequencies are very small, with a maximum difference just under 3 dB (Table 4). These results reflect a high degree of consistency in the procedures of the DTH laboratory.

## SOURCES OF VARIABILITY

It is unclear to many and surprising to others why reputable, nationally recognized laboratories with highly qualified staff are unable to obtain comparable real-ear attenuation at threshold data on the same hearing protector using the same rigorous measurement procedure. The dominant reason is variability. Constant attention to all factors is required to even approach the limits of accuracy and repeatability of the measurements. As noted earlier, the sources of variability are numerous and many cannot be eliminated. Both subjective and physical factors are involved. Subjective factors range from changing levels of individual subject motivation to slight changes over time in the subject's physiological hearing threshold levels. Physical factors range from intermittent changes in ambient noise to fluctuations in the performance of any of the electronic instrumentation. Measurements made with acoustic test fixtures (dummy heads), utilized to eliminate subjective sources of variation, usually experience some improvement in repeatability over subjective measurements. However, the degree of repeatability obtained within these physical measurements is usually less than would be measured using responses of human subjects. Various amounts of variability are always present to influence the data. It is this variability that interferes with repeatability.

Sources of variability in laboratory measurements of hearing protector attenuation are noted in terms of the measurement standard, facilities and equipment, experimenter, procedure, subjects, and hearing protection devices (6, 11). Both random and systematic differences are present in several forms. Many of these individual sources have very small to negligible effects; however, they can accumulate to interfere with true measurements and repeatability. In most cases, the sources are merely noted and their potential effects are apparent. More extensive discussions of each issue would provide little additional benefit. The variability characteristics of the true population are represented differently by each separate group of subjects.

### Measurement Standards

Substantial effort and review by scientific and technical experts go into the development and establishment of a national or international measurement standard, frequently requiring several years. Often, data are not available to fully support all specifications and some are attained on the basis of limited data, experience, and logic of the experts and practitioners. Some standards are conditionally approved for a few years to enable the acquisition of data and experience with their use to fully support establishment of the final standard. Once established, situations may exist in the laboratories that obstruct its proper and full implementation. Details of the standard may be unclear, misinterpreted, or even ignored by the experimenter. The uncertainty of ambiguous portions of standards certainly breeds interpretation; however, this also occurs when the standard is not ambiguous. The standard may not be sufficiently complete for some experimenters, who proceed without full understanding. Standards define instrumentation specifications required to produce the expected result, yet sometimes inadequate equipment is assumed to be satisfactory and is used. Very infrequently, the standard contains an error. Also, technology may improve, causing something in the standard to become obsolete or no longer adequate.

## Procedures

Various random and systematic biases in this replication measurement procedure must be randomized to minimize variability. Among these are random selection of the subjects, distribution or assignment of the devices being tested, orders of test variables, presentation of test signals, and time of testing during the day. Decision making on all issues should be based on well-defined guidelines to ensure consistency throughout. Sizing of the insert, semi-insert, and earmuff devices as well as the fitting procedures must comply with the standard and be implemented precisely the same for all subjects, free from influences of experimenters. Criteria for repeating a trial must be well-defined and practiced. The level and manner in which the fitting noise is used must also be the same for all subjects and all fittings of hearing protectors. The number of test subjects, orders of presentation, and repeat trials may influence mean and standard deviations, i.e., 10 subjects with 3 repeat measurements, 20 with 2, 20 with 1, 24 with 1, or others.

## Experimental Subjects

One of the most difficult factors to control is the volunteer subject, the other is the experimenter. Each group of subjects represents the true population to a different degree. Hearing protection devices do not provide exactly the same fit or sound attenuation for all subjects; both vary from person to person and from fit to fit. The subject factors that can affect performance are present before as well as during the test sessions. Excessive noise exposure prior to visiting the laboratory could affect hearing threshold level measurements. In the laboratory, the subject performs a psychomotor threshold of hearing task that seems simple but requires persistent attention and concentration for extended periods of time. Hearing threshold level variations occur with fluctuations in attention, concentration, and motivation of the subject as well as with fatigue. Slight variations occur over time in the subject's physiological hearing threshold levels as well as in the subject's criterion of threshold during the method of adjustment plotting procedure. Hearing threshold level variations of 2 to 3 dB are inherent in the determination of audiometric thresholds. Subjects differ in their ability to plot their hearing thresholds, to learn to properly fit particular hearing protection devices, and to understand instructions from the experimenter. Both the bone conduction and the mechanical impedance of the skin and flesh vary among subjects. Anatomical factors such as size and configuration of the head, conformation of the external ear canals and the head around the pinnae, and even the density of the hair around the pinnae and on top of the head can interfere with the proper fitting of the hearing protection devices. Subject motivation is particularly important during all testing sessions and can be influenced by numerous other factors and/or persons in the test laboratory area.

## Experimenter

No two experimenters are the same. They differ in motivation, experience, interactions with subjects as a group and with individuals in the group, in testing procedures, in preferences for items of equipment, in personal habits developed by the practice of testing subjects, and perception of the actual purpose of the test. Experimenter attitude and behavior can change with situations outside and inside the laboratory such as performance on "good days" and on "bad

days." Experimenters' interactions influence the motivation of individual subjects differently in neutral, negative, or positive ways. Subjects may not obtain the same understanding of experimenter instructions even when they are memorized and/or read aloud by the experimenter. The use of manufacturer's instructions on the fitting and use of a hearing protection device is usually interpreted and described by the experimenter. Some experimenters may have preferences for certain hearing protection devices that are unintentionally conveyed to the subjects. Although the measurement standards require basic mean and standard deviation data, all experimenters do not use the same calculation procedure to obtain these values, particularly when dealing with 10 subjects and three repeat measurements.

### Facility and Instrumentation

The atmosphere of the test location can vary widely in areas that range from an unpleasant, bare-bones, poorly-lighted laboratory area and test chamber to one furnished similar to a comfortable family room or den. The subject chair and response system must be sufficiently comfortable and easy to use to be essentially transparent to the subject. Full compliance with the instrumentation specifications and the test space calibrations is essential. Instrumentation and systems replaced during a study are sometimes mistakenly assumed to remain within specifications and recalibration is not accomplished. Non-compliances can go unreported by the experimenter. Lack of periodic checks of measurement system performance at different times of day and over reasonable time periods result in drifting and nonlinearities of instrumentation that are not detected, and experimenters mistakenly believe they are in compliance. During visits to other laboratories, the author has personally observed hearing protector attenuation measurement systems in operation that did not conform with the current national measurement standard and were reported by the host as being in full compliance with the current standard.

Full conformance to all specifications of a standard is required to allow data to be reported as collected under the standard. It is inappropriate to report using the standard when even a single requirement has not been met. The very explicit specifications are intended to provide better repeatability than with unspecified systems and procedures. Satisfying the specifications for implementing and operating under current hearing protection measurement standards is expensive, difficult, time consuming, and requires special instrumentation. As a consequence of such things as instrument or test space limitations, some measurement facilities are unable to totally comply with the appropriate standard. Most of these, but not all, report the non-compliant element of the facility and proceed with their measurement programs. It is incorrectly assumed by some investigators that non-compliance with some specifications has a negligible effect on results.

Frequency distortion from an overdriven loudspeaker at the 125 Hz test signal could produce a distortion product at 2000 Hz. This signal is below the 125 Hz hearing threshold but above the 2000 Hz threshold where the ear is much more sensitive. The response to the 2000 Hz signal will be recorded as the response to the 125 Hz signal. This incorrect value will differ from values obtained with the undistorted 125 Hz conditions at other laboratories. Any non-compliance with a standard should be viewed as contributing to the variability.

Table 5. Reported elements of hearing protector attenuation measurement systems that were not in compliance with national and international standards during testing in some individual laboratories within the interlaboratory studies. Individual laboratories used different types of sound fields during the interlaboratory studies.

Non-compliant elements		Laboratory				
		I	II	III	IV	V
<input type="checkbox"/>	Rise and fall times of the test signals exceeded standard	X				
<input type="checkbox"/>	Deviations in sound field	X		X	X	
<input type="checkbox"/>	Ambient noise			X		X
<input type="checkbox"/>	Harmonic distortion			X		
<input type="checkbox"/>	No measurements with directional microphone				X	
<input type="checkbox"/>	Arithmetic corrections to measured data			X		
Types of sound field						
<input type="checkbox"/>	Progressive wave	X		X		
<input type="checkbox"/>	Nondirectional random incidence		X		X	X

Specific non-compliances reported by individual participants in the interlaboratory studies are summarized in Table 5. One intercomparison study reported as many as four separate non-compliance incidents. Another experimenter stated that the standard requirements for practice sessions were loosely interpreted and not fully implemented, and that they "tried for a better fit on repeat measurements" while staying within the guidelines. It is likely that other noncompliances occurred and were judged by the experimenters not to influence the data. No information is provided in Table 5 to identify which individual laboratories reported noncompliance. The numbers of the interlaboratory studies I through V (in Table 5), have been scrambled and do not correspond to the chronological order of presentation in the text.

### Headband Force Measurement

Most national and international standards on the subjective evaluation of hearing protectors require that the headband force be measured on all circumaural devices. Some offer guidance on the development of an appropriate system and others only require that a measurement be conducted and reported in the results of the evaluation. The force or pressure of an earmuff against the sides of the head is measured to estimate the discomfort/comfort of the device and the change (reduction) in force, if any, with short time use by the subject. Headband force measurement systems differ greatly from laboratory to laboratory, ranging from devices fabricated in the facility using sensors such as strain gauges to common scales designed for use by meat markets and grocery stores. The variety of calibration systems for these units matches that of the force measurement systems. Consequently, with very few exceptions, the measurement systems, calibration systems, and procedures are too different at this time to expect repeatable measurements among the laboratories. A requirement is essential that measurement laboratories desiring corresponding data use identical systems and procedures to measure headband force if data are to be compared among laboratories.

## Hearing Protection Devices

Indispensable attributes of a hearing protection device are ease of use, comfort, and wearability features; when the hearing protector is not comfortable, it will not be worn. Although the effects on comfort of long wearing times cannot be reliably determined during the relatively brief laboratory test, devices that cause discomfort can be identified during those periods. Features such as weight, headband force, incorrect size, and unsatisfactory configurations can influence subject acceptability and performance. Sizing and fitting of premolded inserts provide different amounts of attenuation depending upon depth of insertion, an oversized or undersized earplug, and retention in the inserted position during the duration of the tests. Depth of insertion is important for all inserts; however, sizing is less of a problem with foam, malleable, or glass wool materials than with premolded types of earplugs. It is very difficult to obtain the same acoustic seal in the ear canal with repeat fittings of both premolded and non-premolded devices. Subjects require different amounts of training/practice to obtain a proper fit with the device under test; this training is not always adequate or provided. Manufacturer's instructions are very important for proper fit of insert devices, but are often unsatisfactory. Full reliance on the general instructions of the experimenter may be inadequate. Subject fit relies only on manufacturer's written instructions in the recently approved Method B in S12.6-1997. The available attenuation of devices will not be obtained in the Method B measurements with manufacturer's instructions that are not clear and easy to achieve. Subtle dissimilarities are found among samples of hearing protection devices from different production lots, storage, aging, temperature conditioning, and handling by the experimenter. Some earmuffs are not retained well when the head is moved quickly or the user looks towards the ground or overhead. Some do not fit properly against the head immediately below and behind the pinnae. Headband force often decreases with wearing time (reducing protection). Ideally, the experimenter should determine if headband force remained constant during the measurement periods and if performance changed with increasing wearing time.

The preceding "list" does not contain all possible or potential sources of variability in the standard measurement process. However, it should provide some explanation for our failure to achieve the theoretical goal of obtaining the same data from a device measured with the same procedure in different places. It should also provide those who are not directly involved with the measurement process an understanding of the multiple factors and their interactions involved in the implementation of this difficult task.

## COMMENTS

The preceding text was drawn from data and experiences with the measurement of hearing protection devices from the mid 1950s to mid 1997, when the latest standard measurement procedure was established. The between-laboratory attenuation mean and standard deviation data over that time have varied too widely to be used interchangeably. At what level of variability are attenuation data determined to be the same or sufficiently similar to be used interchangeably for developing effectiveness metrics such as NRR or SNR? Should comparisons of mean, adjusted mean, effectiveness rating, or some other metric be used to determine interchangeability? The information in Figures 1, 6, and 8 affirms that the groups of

interlaboratory mean data are well separated from one another. The within-interlaboratory data are more similar but still show relatively large differences. The adjustment of mean data from different laboratories by subtracting standard deviation values often shows larger dispersions than the unadjusted means. The single number effectiveness rating is furthest from the raw data and is not appropriate as a comparison metric. It is possible that some criterion level of variability for interchangeable data could be defined and adopted. However, it is the author's opinion that there is a very low probability, if any, that data between laboratories will ever be practically interchangeable using current or future psychoacoustic measurement procedures. When data between individual laboratories are interchangeable, it is an exception.

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Table 6. Mean attenuation of four repeat measurements of the EAR earplug and three repeat measurements of the Bilsom earmuff in the NPL laboratory. EAR data reveal slight subject learning from test 1 and high repeatability with no statistically significant differences among tests 2, 3, and 4. Bilsom data also show this level high level of repeatability among tests 1, 2, and 3.

	Third-octave band center frequency (Hz)									
	63	125	250	500	1000	2000	3150	4000	6300	8000
<u>EAR tests</u>										
NPL1	21.7	22.4	22.1	24.9	26.4	31.5	38.5	40.6	37.9	35.6
NPL2	23.6	25.4	26.1	28.2	27.2	32.6	40.4	41.9	41.7	37.3
NPL3	23.6	24.8	26.3	27.5	28.0	32.2	39.7	41.4	40.4	37.3
NPL4	25.4	26.6	28.5	29.8	31.2	33.8	40.3	41.4	39.7	39.1
<u>BILSOM tests</u>										
NPL1	13.3	9.2	14.8	22.0	31.9	34.9	43.2	43.7	41.7	40.3
NPL2	14.0	11.7	15.2	22.5	32.3	33.3	43.4	43.6	39.9	39.4
NPL3	13.4	10.5	16.0	22.5	32.0	33.6	42.0	42.1	38.0	38.4

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Many individual laboratories obtain highly similar results on repeat measurements. The EAR mean attenuation data from the Nordic study participants was the most consistent among the interlaboratory studies. The ranges at each test signal for the four laboratories are less than 5 dB except at 4000 Hz (5.6) and 8000 Hz (5.4). The interlaboratory mean attenuations are within 3 dB of the mean attenuations of the four participants, which is a good representation of their individual data. DTH shows close agreement among earmuff data measured more than one year apart (Table 2). NPL shows excellent retest agreement for the EAR earplug and the Bilsom earmuff with no statistically significant differences among the tests (Table 6). Several years ago, the author conducted an informal analysis of repeat measurements in the same laboratory of the attenuation of the V51R earplug. Ten sets of data showed very high reliability (each using 10 subjects, three repeat measurements and experimenter fit) of measurements made at different times over a 20-year period, in three different test rooms, and with different experimenters and groups of subjects. The differences between the means were less than three decibels at all test frequencies. The different facilities and procedures complied with the existing Z24.22-1957 standard. Unfortunately, the information was not archived and is no longer available for further review.



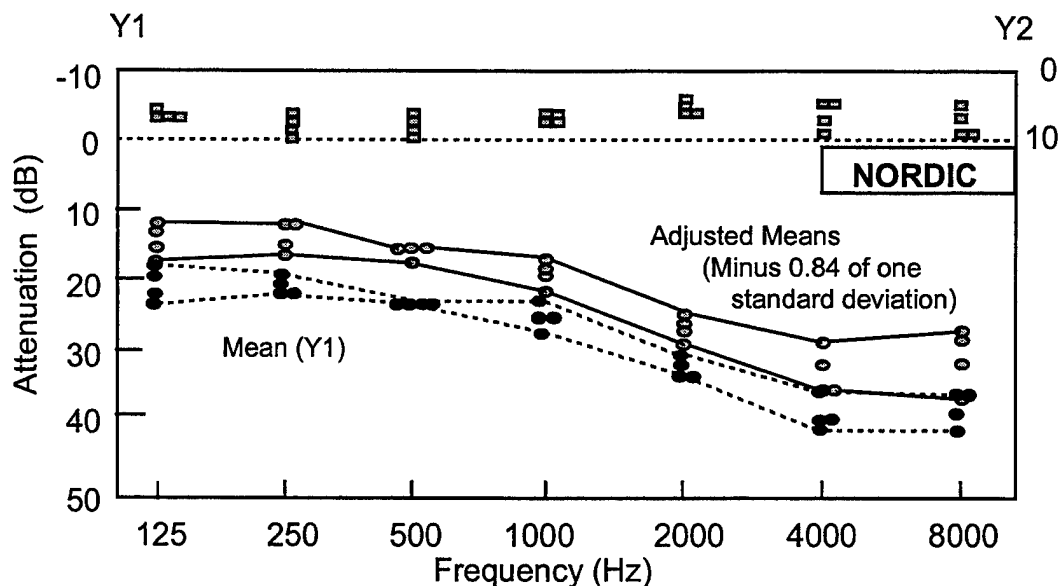


Figure 9. The original EAR means and standard deviations measured in the Nordic study and the adjusted means. The means were adjusted to increase the portion of the population protected by the measured device by subtracting 0.84 percent of one standard deviation (European adjustment value) from the original mean value at each test frequency.

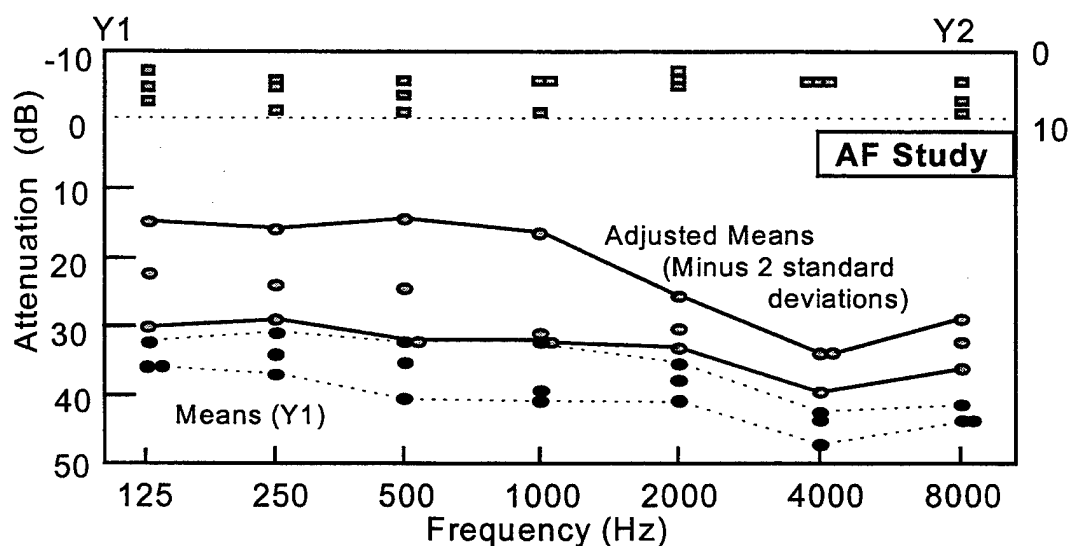


Figure 10. The original EAR means and standard deviations measured by the individual laboratories in the Air Force survey and the adjusted means. The means were adjusted to increase the portion of the population protected by the measured device by subtracting two standard deviations (EPA adjustment) from the original mean at each test frequency. The adjusted mean values show substantially greater dispersion than the unadjusted mean values.

It is apparent that the dispersion of mean attenuation data is usually increased after its adjustments for protection of populations. The most consistent EAR mean data among the

interlaboratory studies (Nordic study) were adjusted to obtain the common European protection performance of 80 percent of the population. This was accomplished by subtracting only 0.84 percent of one standard deviation from the mean at each frequency (20). The original means and standard deviations and the adjusted means are shown in Figure 9. The ranges of adjusted data remain consistent at the low frequencies and disperse a little more at the higher frequencies with an average increase of about 2 dB. Subtracting two standard deviations from the means, as required in the U.S., further increases the spread of the data. The adjusted means of the Air Force study data show substantially greater scattering at most frequencies than the unadjusted means (Figure 10). The adjustment of mean attenuations by subtracting standard deviation values can produce much greater dispersion of data than the unadjusted mean attenuations.

Earplug data are strongly influenced by the type of fit of the hearing protector. Data obtained with a true experimenter fit (AF study), in which the size selection and insertion/application of the hearing protector are accomplished by an experienced experimenter typically reflect the highest sound attenuation. Data obtained with the naive subject using only fitting instructions provided by the manufacturer, with no assistance from the experimenter, display the lowest attenuation. The mean and standard deviation values obtained with the Subject Fit method in the interlaboratory study are within the ranges of the data of the four experimenter-assisted fit study groups. Subject fit data will improve as manufacturer's instructions are revised to facilitate hearing protector selection and fitting by naive subjects. The difference in attenuation attributed to fitting procedures can exceed 30 dB, or more, at some frequencies for individual subjects.

Many nations, such as those participating in the Nordic and EEC studies, Australia, and New Zealand have only one laboratory that conducts all hearing protector measurements for national and commercial purposes. This concept has the advantage noted earlier of better reliability of repeat measurements within rather than between laboratories as demonstrated by the EEC and Nordic data. Measurements of hearing protector attenuation are accomplished in many different places in the United States, such as government laboratories, hearing protection device manufacturer laboratories, independent testing laboratories, universities, institutes, and commercial companies. This large number of testing facilities increases the opportunity for more variability in the data from measurements that may or may not comply with the current standards. The measurement of hearing protectors for marketing purposes must be accomplished by independent laboratories that provide unbiased evaluations for the hearing protector manufacturer (13). At the time of this writing, only three laboratories are accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) (18). In the future, it is likely that regulations will require that evaluations of hearing protectors be measured only in NVLAP accredited laboratories.

Up to this point, the focus has been on the mean and standard deviation values of sound attenuation. This focus would be adequate if this were the end use of these data. However, as noted earlier, the mean data are manipulated to provide effectiveness ratings that are used for the protection of people exposed to noise. The manipulations involve reductions of the mean values by amounts related to the sizes of the standard deviations. In normally distributed population data, the mean values are expected for about 50 percent of the distribution. The mean minus one standard deviation value is expected for about 84 percent of the population and mean minus two

standard deviations for about 98 percent of the population. Mean hearing protector attenuation data in the United States are reduced by two standard deviations in compliance with noise exposure regulations and hearing conservation requirements to serve about 98 percent of the population. The ISO standard provides options for protection of 75 to 98 percent of the population covered by subtracting a multiple of the standard deviation from the mean attenuation. The adjusted mean values are used in the development of the effectiveness rating of the measured hearing protector.

The hearing protector effectiveness rating in the United States is the Noise Reduction Rating, a single-number value intended to describe how much an overall noise level is reduced by the protector. This value is calculated using the hearing protector mean minus two standard deviation attenuation values. The NRR is used to estimate the level of noise under a worn hearing protector by subtracting its value from the C-weighted level of the environmental noise. A hearing protector with an NRR of 15 dB would reduce an ambient noise of 100 dBC to 85 dBA at the ear under the earmuff. The NRR can also be subtracted from dBA measurements, but a 7 dB correction factor must be subtracted from its value. In Europe, the Single Number Rating, similar to the NRR, the High-Middle-Low (HML) Rating, and the Assumed Protection Value (APV) are available. The HML measurement method provides three rating values for each hearing protector that allow the selection of a hearing protector for use in low (L), middle (M), or high (H) frequency noise environments. Although this method allows a hearing protector to be selected for the noise frequency region where it is needed, it is not popular in many places because the computation procedure is not simple. The APV calculation provides a prediction of the overall effective noise level at the ear under the protector. It is calculated separately for each selected percentage of the population to be covered (20).

The EPA regulation requires the subtraction of two standard deviations from the means obtained with experimenter-supervised fit procedures for the calculation of the NRR. The S12.11 uninformed subject fit method of S12.6-1997 recommends subtraction of only one standard deviation to accommodate the smaller mean attenuation values obtained with this fitting procedure. These manipulations are also implemented on the assumption that the reduced mean values serve larger portions of the population. The OSHA (1979) assumption that the user population obtained amounts of attenuation that corresponded to those obtained by subjects during laboratory tests is incorrect and was noted earlier (7).

The standard deviation reveals the dispersion of the data around the mean. Two hearing protection devices with identical mean attenuation values appear to provide the same attenuation. However, the mean data are adjusted by the standard deviations of the data set to obtain the effectiveness rating. Consider that both devices have an overall mean attenuation of 22 dB. The overall standard deviation of one is 3 dB and the other is 7 dB. Subtracting two standard deviations from the mean of 22 dB produces an overall attenuation of 16 dB for the first and only 8 dB for the second hearing protection device. This difference in the adjusted sound attenuation is reflected in the effectiveness rating such as the NRR.

NIOSH periodically publishes a compendium of hearing protection devices and their performance characteristics that includes mean attenuation and standard deviation values (16, 19). The most recent publication (20) describes 241 different devices consisting of earplugs,

semi-aural devices, earmuffs, and hard-hat mounted earmuffs. The reported standard deviations among these devices are very similar, seemingly somewhat independent of the type of protector, and relatively small with an estimated average of only about 3 dB. Standard deviations as high as 5 to 6 decibels or above appear infrequently in the compendium. These values are significantly less than those obtained from the interlaboratory studies. The compendium hearing protector attenuation information was obtained by independent laboratories conducting tests for the manufacturers. This independent test information is required for compliance with EPA requirements for labeling and marketing hearing protectors in the U.S. The test information was provided by the hearing protector manufacturers and does not represent data from measurements made by NIOSH.

In view of all of this, what should be expected from measured hearing protector attenuation data? We should expect just about what we see in the interlaboratory study data. The facilities were, and are, among the top acoustic laboratories in the world. The experimenters in the intercomparison studies were highly qualified to accomplish the measurements and to ensure compliance with the measurement standards, with few, if any, exceptions. The motivation was presumed good and results of their efforts were known to have important impacts on the evaluations of hearing protectors and their effectiveness ratings within and among participating laboratories and, in some cases, nations. Some interlaboratory studies were more consistent than others and some individual laboratories within the interlaboratory studies were better than others. The measured results represent the best data that could have been attained under the given circumstances. The data represent accurate (not meaning valid) responses of subjects at the time and under the conditions of the studies.

A 1998 repetition of the intercomparison studies among these top laboratories would be expected to, again, obtain the best data under the existing circumstances. Overall, the data would not be identical nor would they be expected to show significant reductions in the variability from those in past studies. A criterion, such as minimum differences between sets of data, to allow the data to be used interchangeably should not be expected. NPL within-laboratory data in Table 6 shows no statistically significant differences among three repeat measurements of an earplug and three repetitions of an earmuff. However, this within-laboratory performance is unlikely to occur with any frequency between laboratories. It is considered unreasonable to expect the various laboratories in countries such as the U.S. to achieve this level of performance with present measurement procedures.

One of the most urgent needs is the establishment of a world-wide, practical measurement procedure that will accurately predict the hearing protection an individual obtains in the noisy workplace. The ability to develop an accurate measurement procedure does not, in itself, assure the effectiveness of its application in real-world situations. In the final analysis, it will still be necessary that the hearing protector be comfortable, fitted properly, and worn in the noise to prevent noise-induced hearing loss. Some prototype portable systems have been developed that make measurements with the employee wearing the hearing protector in the workplace. However, these systems are not yet practical for application to numerous individuals in the broad hearing conservation populations. The Subject Fit measurement procedure described in the S12.11 interlaboratory study has made significant strides toward estimating real-world attenuation of hearing protectors. This new method, a modified real-ear attenuation at threshold

procedure, involves significant changes from current standards in the selection of volunteer subjects, the role of the experimenter, and the fitting of the hearing protection device. The S12.11 goal was satisfied with this method, which estimates protection that can be, or is being, obtained by the top 10 percent to 20 percent of today's hearing conservation programs. The amount of attenuation obtained is significantly less than that obtained with all other current measurement standards. The lower attenuation values are much more realistic than those obtained by all other measurement procedures; however, they still do not estimate or predict the real-world attenuation in the workplace.

The Subject Fit method has been approved by the American National Standards Institute and endorsed by several scientific and medical organizations. It is not authorized by the federal government. Although it appears that the EPA recognizes the value of this new procedure, regulatory action by the federal government is required to make changes in the current EPA hearing conservation regulation that would endorse the subject fit procedure. When this occurs, the impact could be momentous on hearing conservation programs that must deal with the sudden, significantly reduced noise reduction ratings of hearing protection devices that are already in use. For the present, the S3.19-1974 method cited earlier remains the mandated procedure for labeling and marketing of hearing protectors in the U.S.

This report addressed the variability of sound attenuation performance data of hearing protection devices and its role in developing hearing protector effectiveness ratings such as the NRR. It did not address numerous other important factors about hearing protection and the prevention of noise-induced hearing loss. It is agreed among hearing conservationists that the most important features of hearing protection devices are comfort, wearability, and ease of use as well as noise exclusion. The Task Force on Hearing Protector Effectiveness established by the National Hearing Conservation Association published its recommendations in the May 1995 issue of Spectrum (17). Although it is not related to the measurement or evaluation of hearing protectors, it is included here because of its importance to the prevention of noise-induced hearing loss. A critical recommendation from the Task Force that merits frequent repetition is: "No single hearing protection device characteristic, such as the attenuation as represented by single number metrics such as the NRR, or any other feature should be the sole reason for the selection of the hearing protector. All relevant factors should be considered. The most important is the ability of the wearer to achieve a comfortable noise-blocking acoustic seal which can be consistently maintained during all noise exposures." (10)

## SUMMARY

National and international hearing protector attenuation measurement standards have been established with the expectation that different testing facilities using these standards should obtain the same or similar results. Hearing protector attenuation data independently collected with procedures that comply with these standards do not show the expected levels of similarity or repeatability.

The major obstacle to the duplication of data among laboratories is the pervasive variability in the measurement systems, procedures, and personnel. Many sources of variability can be minimized by the diligent efforts of the experimenter. Other sources of variability are

intrinsic to the situation and are not subject to actions of the volunteer subject or the experimenter.

Two of the major sources of variance in these measurements are the subject and the experimenter. No two subjects or experimenters are alike; no two testing sessions are completely alike.

Primary sources of variability with earplug data are the type of device (i.e., preformed, formable), material (i.e., cotton wool, foam, silicone), size, and fit. Fewer sources of variability in the measurement of earmuff devices facilitate better repeatability than with earplug devices both within and among laboratories.

The real-ear attenuation at threshold is the psychometric method employed in hearing protector measurement standards world-wide with only minor differences among user nations. Human subjects define the lowest levels of sounds that are heard with ears open and ears occluded by the hearing protector. Attenuation is defined as the difference between the open and occluded ear hearing threshold levels. This procedure has high face validity.

Criteria do not exist to determine when data from different sources are similar enough to be interchangeable. Inspection of hearing protector attenuation data suggests that there is a very low probability, if any, that between-laboratory study data will ever be interchangeable.

The new Subject Fit method adopted by the American National Standards Institute in 1997 provides mean attenuation values of hearing protectors that are closer to those obtained with the hearing protector in the workplace. The Subject Fit method does not estimate or predict the real-world attenuation of hearing protectors.

Repeat measurements in the same laboratory with the same experimenter and subjects and without an additional learning effect should provide essentially the same results with means that remain within a couple of decibels of one another.

Although compliance with national standards is mandated, it appears that some laboratory measurements continue to be made with facilities and procedures that do not fully conform to the requirements of the standard. Nonconformance contributes to variability.

Most nations have all hearing protection devices measured in the same laboratory for both government and nongovernment purposes. This concept eliminates the requirement for and potential differences between multiple measurement facilities in the same country. It is perceived to be an equitable practice with all hearing protectors receiving the same treatment.

Throughout this report numerous summarizing-type comments have been made about such things as measurement, data, metrics, and variability. These comments were intended to reflect trends, patterns, and general conclusions indicated by data and personal experience. There is a vast hearing protector sound attenuation database that has been collected over the past 50 years. Although exceptions to many of the comments can be easily found, the trends and general observations are pertinent.

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## APPENDIX A

### EAR MEAN AND STANDARD DEVIATION DATA REPORTED FOR INDIVIDUAL LABORATORIES WITHIN THE FIVE INTERLABORATORY STUDIES

Air Force Survey		Frequency (Hz)						
		125	250	500	1000	2000	4000	8000
AF AMRL	Means	37	38	41	41	39	43	44
	SDs	3	4	4	4	4	4	7
Michael & Assoc.	Means	33	35	37	40	41	48	44
	SDs	4.7	4.5	5.4	3.9	3.3	4.2	3.8
Ft Rucker	Means	31	32	33	33	37	44	42
	SDs	7.4	7.5	9	8.8	4.8	4.4	9.4
Average Means		33.7	35	37	38	39	45	43.3
Average SDs		5	5.3	6.1	5.6	4	4.2	6.7

EPA Study								
Ft Rucker	Means	30.1	31.5	32.3	33	35.9	41.8	43.3
	SDs	6	6.8	7.2	6.2	2.9	3.4	5.3
EAR Lab	Means	31.3	34.5	38.2	37.9	34.7	43.6	46.5
	SDs	4.4	4.8	4.5	4.4	3.6	2.6	3
Worcester Poly	Means	29.5	30.4	32.3	32.5	34.9	43.5	43.5
	SDs	5	5.9	6.8	5.4	3.7	3.1	6.4
Navy-Penscola	Means	29.3	32	34.4	33.9	34.5	38.3	41.8
	SDs	6.3	7	5.8	6	4	3.1	4.5
Kresge	Means	27.9	30.2	31.3	32.3	34.8	40.2	41.1
	SDs	4.1	3.6	3.3	3.6	2.8	3.0	4.3
Intest Lab	Means	34.4	35.5	37.9	35.6	36.1	40.4	46.7
	SDs	3.3	4.4	4.1	3.4	4	3	3
Teter & Assoc.	Means	35.6	36.5	38.7	37.6	36.9	44.5	45.6
	SDs	3.6	2.9	4.1	4.2	4.9	3.6	4.4
Michael & Assoc.	Means	29.4	34.5	37.3	39.6	41.2	47.3	45.8
	SDs	3.3	2.2	1.3	2.2	2.5	2.7	2.7
Average Means		30.9	33.1	35.3	35.3	36.1	42.5	44.3
Average SDs		4.5	4.7	4.6	4.4	3.6	3.1	4.3

EEC Study		Frequency (Hz)						
		125	250	500	1000	2000	4000	8000
DTH	Means	26.7	28.9	31.8	31.7	37.2	45.3	44.2
	SDs	8.4	9.4	10.2	8.3	4.5	5.9	8.4
INRS	Means	18.8	20.4	21.9	24.3	28.7	41.9	34.9
	SDs	3.6	3.6	5.5	4.3	3.6	4.6	6
NPL	Means	25.4	26.1	28.2	27.2	32.6	41.9	37.3
	SDs	8.6	8.8	10.2	8	5	5.2	7
PTB	Means	29.1	29.3	31.3	30.3	35.5	44.1	42.3
	SDs	5.1	4.9	4.2	4.6	4.8	4.7	5.5
TNO	Means	24.8	26.2	27.7	28.6	29.9	37	39.2
	SDs	8.7	7.8	8.3	8.5	3.8	5.2	6.8
Average Means		24.9	26.1	28.2	28.4	32.8	42	39.6
Average SDs		6.9	7.6	7.7	6.7	4.3	5.1	6.7

Nordic Study								
DTH	Means	19.3	19	22.4	23.7	31.6	35.3	35
	SDs	7.1	8.1	7.9	7	5.1	7.2	8.5
SF	Means	21	21	21.5	25.6	32.3	38.8	37.2
	SDs	6.7	5.9	6.7	5.9	3.7	4.9	7.4
N	Means	17.8	19.6	22.3	22.5	30.7	38.9	34.6
	SDs	6.5	9.1	8.5	6.7	6.1	8.6	8.7
S	Means	22.3	21	22.5	23.8	29.5	39.6	40.4
	SDs	5.7	6.7	6.2	6.3	5.6	5.3	5.3
Average Means		20.1	20.2	22.1	26.7	31	38.2	36.8
Average SDs		6.5	7.5	7.3	6.5	5.1	6.5	7.5

S12.11 Study								
EARCAL	Means	22.5	23	25.7	26.8	33.6	41.6	41.2
	SDs	5.3	5.4	6.6	6.1	4.8	4.8	7
Ft Rucker	Means	18.8	18.9	20.3	19.5	27.1	34.9	33.4
	SDs	7.7	6.3	6.8	6.3	4.9	6	7.5
NIOSH	Means	23.7	25.1	26.2	27.2	31.9	40.7	42
	SDs	6.8	6.9	7.6	7.3	4.3	6.1	7.5
WPAFB	Means	17.9	19	21	24.7	29.9	35.6	34.6
	SDs	6.6	6.2	6.5	5.4	4.9	5.7	8.2
Average Means		20.7	21.5	23.3	24.6	30.6	38.2	37.8
Average SDs		6.6	6.2	6.9	6.3	4.7	5.7	7.6

## APPENDIX B

### V51R MEAN AND STANDARD DEVIATION DATA REPORTED FOR INDIVIDUAL LABORATORIES WITHIN THREE INTERLABORATORY STUDIES

Air Force Survey		Frequency (Hz)						
		125	250	500	1000	2000	4000	8000
AF AMRL	Means	25	24	26	28	36	34	38
	SDs	2.6	3.8	3.7	4.1	3.3	5.0	7.0
Michael & Assoc.	Means	22	23	25	30	33	39	36
	SDs	6.1	6.1	6.5	4.5	5.8	5.7	6.0
Ft Rucker	Means	23	21	23	25	33	31	30
	SDs	7.4	5.2	5.4	6.4	5.8	6.8	9.2
ARCON	Means	18	21	23	26	32	43	39
	SDs	6.0	3.0	4.0	4.0	3.0	3.0	4.0
Average Means		22	22	24	27	34	37	36
Average SDs		5.5	4.5	4.6	4.8	4.5	5.1	6.6

EPA Study								
Ft Rucker	Means	24.4	23.4	24.8	25.1	31.6	27.8	27.0
	SDs	7.3	7.0	5.9	5.3	4.4	4.1	6.1
EAR Lab	Means	25.1	24.8	24.7	26.0	29.3	31.8	33.3
	SDs	5.8	5.9	6.5	5.5	4.4	7.4	10.5
Worcester Poly	Means	25.7	25.7	24.4	26.0	33.1	33.7	31.1
	SDs	6.2	6.4	6.6	5.2	6.3	6.4	8.9
Navy-Pensacola	Means	22.8	24.7	22.9	25.2	29.6	31.1	33.0
	SDs	6.9	5.8	6.1	6.6	5.4	5.7	8.6
Kresge	Means	23.5	24.7	25.1	27.7	29.7	30.4	31.8
	SDs	3.1	3.2	2.6	3.3	4.2	4.3	4.5
Intest Lab	Means	22.6	23.6	24.0	25.1	33.5	30.3	31.8
	SDs	4.4	4.2	6.1	5.1	4.8	6.2	8.4
Teter & Assoc.	Means	26.5	26.4	26.9	28.3	31.3	31.0	31.9
	SDs	3.1	3.6	3.5	2.5	3.1	3.0	3.0
Michael & Assoc.	Means	20.4	23.2	25.4	29.0	34.9	38.6	38.7
	SDs	2.2	2.2	2.3	1.8	2.0	2.3	2.8
Average Means		23.9	24.6	24.8	26.6	31.6	31.8	32.3
Average SDs		4.9	4.8	5.0	4.4	4.3	5.0	6.8

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S12.11 Study		Frequency (Hz)						
		125	250	500	1000	2000	4000	8000
EARCAL	Means	14.4	13.7	14.4	16.4	24.7	25.9	19.1
	SDs	10.6	9.5	9.4	10.8	12.6	9.8	10.7
Ft Rucker	Means	11.0	10.5	10.5	11.9	17.6	19.0	15.6
	SDs	8.9	8.0	8.5	8.3	9.4	8.4	9.9
NIOSH	Means	11.2	10.7	10.9	13.6	21.8	22.6	16.8
	SDs	9.6	9.2	9.5	9.1	8.5	6.8	11.8
AF-WPAFB	Means	10.6	9.9	11.3	14.7	22.3	24.7	20.8
	SDs	9.9	10.3	9.9	9.0	8.0	6.6	10.2
Average Means		11.8	11.2	11.6	14.2	21.6	23.1	18.1
Average SDs		9.8	9.3	9.3	9.3	9.7	7.9	10.7

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## APPENDIX C

### EARMUFF MEAN AND STANDARD DEVIATION DATA REPORTED FOR INDIVIDUAL LABORATORIES WITHIN THE FIVE INTERLABORATORY STUDIES

#### Air Force Survey - MSA MARK II

		Frequency (Hz)						
		125	250	500	1000	2000	4000	8000
AF AMRL	Means	15	24	34	36	43	40	35
	SDs	4.0	3.0	3.0	7.0	6.0	3.0	6.0
Michael & Assoc.	Means	19	25	35	42	37	36	35
	SDs	3.8	3.7	4.6	5.7	3.7	4.8	5.4
Ft Rucker	Means	20	26	34	39	35	41	33
	SDs	3.3	3.3	3.4	6.5	5.1	4.5	6.7
Average Means		18	25	34	39	38	39	34
Average SDs		3.7	3.3	3.7	6.4	4.9	4.1	6.0

#### EPA - MSA MARK IV

Ft Rucker	Means	7.6	9.5	16	24.4	24.5	31.4	30.9
	SDs	6.5	10.3	13	9.9	8.9	10.9	9.7
EAR Lab	Means	7.0	12.7	21	29.4	27	32.5	33.1
	SDs	7.6	11.2	10.7	9.4	7.5	9.3	7.8
Worcester Poly	Means	14.4	20.9	28.3	32.7	33.2	40.7	39
	SDs	3.1	4.3	5.2	3.2	3.9	4.4	3.8
Navy-Pensacola	Means	8.3	13.9	20.7	26.2	28.1	32.3	30
	SDs	6.6	8.3	7.4	6.0	5.9	6.1	6.8
Kresge	Means	17.7	18.5	22.9	28.7	29.9	37	34.7
	SDs	6.8	6.4	7.3	5.9	5.4	6.4	6.7
Intest Lab	Means	11.6	20.3	26.2	33.5	33.7	40.9	39.5
	SDs	3.9	4.9	6.1	5.8	3.6	4.4	4.9
Teter & Assoc.	Means	9.2	11	15.9	21.8	23.7	24.7	24.3
	SDs	3.4	3.2	3.9	3.6	3.6	4.0	2.7
Michael & Assoc.	Means	14.2	19.8	25.6	31.3	35	43.2	37.4
	SDs	1.5	2.1	3.2	1.7	2.3	1.9	2.5
Average Means		11.3	15.8	22.1	28.5	29.4	35.3	33.6
Average SDs		4.9	6.3	7.1	5.7	5.1	6.7	5.6

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**Nordic Study - Optac Optigard**

		Frequency (Hz)						
		125	250	500	1000	2000	4000	8000
DTH	Means	5.4	9.3	18.1	23.6	26.3	36.1	30.9
	SDs	3.2	3.5	4.8	2.6	3.8	4.3	6.1
SF	Means	8.0	11.9	20.4	25.5	31.8	39.9	35.7
	SDs	3.4	3.0	2.3	2.1	2.3	4.3	2.9
N	Means	6.7	8.1	19.8	22.3	27.1	40	31.3
	SDs	6.1	3.3	3.6	5.0	5.0	6.6	5.3
S	Means	6.7	9.1	18.5	23.1	27.7	40	35.5
	SDs	3.7	2.5	2.8	2.4	3.8	2.4	4.0
Average Means		6.7	9.4	19.2	23.6	28.2	39	33.4
Average SDs		4.1	3.1	3.4	3.0	3.7	4.4	4.6

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**EEC Study - Optac Optigard**

NPL	Means	9.1	12.5	21.6	25.5	32.7	38.6	30.4
DTH	Means	9.7	9.3	23.6	25.9	34.3	38.9	36.2
INRS	Means	9.4	12.5	21.3	23.6	32.4	31.8	29.6
PTB	Means	9.9	12.6	22.1	25.9	33.3	40.5	33.4
TNO	Means	8.1	9.5	18.8	21.9	28.1	32.3	32.5
Average Means		9.2	11.3	21.5	24.6	32.2	36.4	32.4

Note: No standard deviations were reported for this earmuff in the EEC study report.

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**S12.11 Study - UF-1**

EARCAL	Means	7.6	14.9	21.6	31.3	32.6	36.9	36.3
	SDs	4.0	3.7	3.5	4.9	4.6	5.1	5.1
Ft Rucker	Means	7.4	14	19	25.6	28.6	33.3	32.8
	SDs	3.6	2.4	2.8	4.6	5.4	3.6	4.8
NIOSH	Means	7.7	14.5	21.3	30.3	31.8	38.3	37
	SDs	3.2	2.4	2.6	3.0	2.9	4.2	4.3
WPAFB	Means	7.0	13.3	21.5	30.4	33.6	34.9	34.9
	SDs	3.8	3.0	3.0	3.8	3.1	3.4	3.8
Average Means		7.4	14.2	20.9	29.4	31.7	35.9	35.3
Average SDs		3.7	2.9	3.0	4.1	4.0	4.1	4.5

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**APPENDIX D**  
**PARTICIPANTS IN THE INTERLABORATORY STUDIES**  
**AND THEIR DESIGNATIONS**

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<u>Study</u>	<u>Designation</u>	<u>Laboratory/Institution</u>
<b>AF Study</b>		
	AF AMRL	Air Force Aerospace Medical Research Laboratory Wright-Patterson AFB OH
	Michael & Assoc.	Paul L. Michael and Associates State College PA
	Ft Rucker	U.S. Army Aeromedical Research Laboratory Ft Rucker AL
	ARCON	Address unknown
<b>EPA Study</b>		
	EAR	E-A-R Division Acoustics Laboratory (EARCAL) Indianapolis IN
	Worcester Poly	Worcester Polytechnic Institute Worcester MA
	Navy-Pensacola	Naval Aerospace Medical Research Laboratory Pensacola FL
	Kresge	Kresge Hearing Institute Portland OR
	Intest Lab	Intest Laboratory Minneapolis MN
	Teter & Assoc.	Darrel L. Teter and Associates Denver CO
<b>EEC Study</b>		
	NPL	National Physical Laboratory United Kingdom
	INRS	Institut National de Recherche at de Securite France
	PTB	Physikalisch-Technische Bundesanstalt Federal Republic of Germany
	TNO	TNO Research Institute for Environmental Hygiene Netherlands

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**Nordic Study**

DTH, DK1	Acoustics Laboratory Technical University, Denmark
SF	Institute of Occupational Health Vantaa, Finland
N	The Audiological Laboratory, Rikshospitalet Oslo, Norway
S	Technical University Stockholm, Sweden

**S12.11 Study**

NIOSH	National Institute for Occupational Safety and Health Cincinnati OH
WPAFB	Armstrong Laboratory Wright-Patterson AFB OH

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